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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,482	01/02/2002	Irun R. Cohen	COHEN=42A	5950

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,482	COHEN ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-12 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 4-6, 9-11 have been amended.

Claims 12-17 have been added.

2. Claims 1-7, 8-11, 17 in part and new claims 13-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper of 3/25/04.

3. Claims 8-11, 12 and 17 are under examination being examined to the extent the peptide is either SEQ ID NO:11 or SEQ ID NO:21.

4. Applicant confirms their election and states that the peptides of Groups XX-XXXVI share structural and functional properties and although the peptides include variant structural elements, the peptides are simply different species and are not different inventions (see page 8 of the response). Again, each peptide is distinct and art on one would not be art on the others. In addition, as stated in the restriction requirement, the peptides are distinct from the methods of use. In addition, as stated previously the restriction requirement is deemed to be proper and is made **FINAL**.
It is acknowledged that claims 13-16 are method claims that depend on claim 12 which is limited to the elected sequences of SEQ ID NO:11 and 21 and will be rejoined upon allowance of the product claims.

5. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

6. The following Office Action contains NEW GROUNDS of rejections.

Claim Objections

7. Claims 8-11 and newly added claim 17 are again objected to because of the following informalities: The claims encompass non-elected inventions. Appropriate correction is required.

Rejections Withdrawn

8. The rejection of claims 8-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as pertaining to paragraph 7a of the previous Office action is withdrawn in view of arguments. It is noted that support for the definition of "chemical derivatives" is in paragraph 0044 not 0056-0057 as stated in the response.

Response to Arguments

9. The rejection of claims 8-11 and newly added claims 12 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as pertaining to paragraph 7b of the previous Office Action is maintained.

The response filed 10/26/04 has been carefully considered but is deemed not to be persuasive. The response states that the recitation of "antibodies to p53" in claim 8 is clear and the specification explains that the present invention relates to the "use of an Ab1 anti-p53 mAb to generate an Ab3 anti-p53 response" (see page 10 of response).

In response to this argument, it is still unclear in the claim if the peptide is to elicit antibodies against p53 (Ab1 antibody) to generate an Ab3 antibody as stated in the response. The claims do not distinguish this fact and it is still indefinite.

10. The rejection of claims 8-11 and newly added claims 12 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed 10/26/04 has been carefully considered but is deemed not to be persuasive. The response states that only the species that are examined and not every individual species within the scope of the claim need to be demonstrated and as both SEQ ID NO:11 and 21 are explained to be able to elicit anti-p53 Abs and the specification states that a peptide are preferably 9-30 amino acids the specification has sufficient definition of peptide structure (see page 10 of the response). In response to this argument, it is known that only SEQ ID NO:11 and 21 are being examined, however, the claims encompass the terms "contains" and "containing" which are open language and means the peptides can have other additional sequences. As such the only sequences defined are SEQ ID NO:11 and 21 and there are no other sequences added to these sequences or disclosed in the specification. Thus, applicant has not described any other sequences except SEQ ID NO:11 and 21. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

11. The rejection of claims 8-11 and newly added claims 12 and 17 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 10/26/04 has been carefully considered but is deemed not to be persuasive. The response states that the specification does teach production of anti-p53 antibodies in Example 4 and that mice immunized with peptides V-IX rejected tumors (see page 11 of response). In response to this argument, while the rejection of tumors was seen in the mice with the specific peptides, the IgG anti-p53 antibodies were anti-ids not anti-p53 antibodies. As evidence from Cruse et al (Illustrated dictionary of Immunology, CRC Press, 1995, page 148), antibodies mimic the antigen and are produced by immunizing with an antibody directed to the antigen. In the instant case a peptide from the CDR of an anti-p53 antibody was used as an immunogen and according to the network theory produces anti-idiotype antibodies which mimic the antigen. It is unclear if then the anti-id produces anti-p53 antibodies as stated in the example or if the anti-p53 antibodies are Ab1 antibodies. Accordingly, while the peptides from the anti-p53 antibody can produce anti-ids, there is no showing that peptides that are chemically derivatized lead to the rejection of tumors. In addition, the art (Erez-Alon et al) is clear that not all peptides from a CDR of an anti-p53 antibody can elicit anti-ids and in addition, as evidenced from the response not all anti-p53 CDR peptides can elicit anti-id (see page 11 of response). Thus, even the instant specification does not enable the breath of the claims because it appears that not all CDRs from and anti-p53 antibody can elicit antibodies.

It is noted that the examiner agrees with the interpretation of the sequences of Law as explained in the response.

Thus, the specification does not reasonably provide enablement for a peptide capable of eliciting antibodies to p53 wherein the peptide contains just any sequence of a CDR from just any anti-p53 antibody and salts and chemical derivatives thereof.

Therefore, in view of the lack of guidance in the specification and in view of the discussion above one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

12. The rejection of claims 8-10 and newly added claim 12 under 35 U.S.C. 102(b) as being anticipated by Jannot et al (BBRC 230:242-246, 1/1997) is maintained.

The response filed 10/26/04 has been carefully considered but is deemed not to be persuasive. The response states that the peptides according to the invention are "preferably 9-30 amino acid residues" and the length of the peptides as a VL does not read on the claims (see page 12 of response). In response to this argument, the claims do not require the peptides to be of any particular length and as such the VL does read on the claims. The response further states that Jannot does not teach immunizing with the anti-p53 fragment to induce anti-p53 antibodies or anti-tumor immunity (see page 13 of response). In response to this argument, the claims are to a synthetic peptide which as stated in the rejection are a product by process claims, thus, the method in which the peptides were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability

is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113. In addition, the claims are to products and as such and as stated in the rejection since the peptide is from an anti-p53 Mab (which is the same Mab as applicant used) it would inherently produce anti-idiotypic antibodies.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832

LARRY R. HELMS, PH.D
PRIMARY EXAMINER